IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MALLINCKRODT IP UNLIMITED COMPANY, MALLINCKRODT HOSPITAL PRODUCTS INC., and NEW PHARMATOP L.P.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
AUROBINDO PHARMA USA, INC.,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Mallinckrodt IP Unlimited Company and Mallinckrodt Hospital Products, Inc. (together, the "Mallinckrodt Plaintiffs") and New Pharmatop L.P. (collectively, "Plaintiffs") for their Complaint against defendant Aurobindo Pharma USA, Inc. ("Aurobindo" or "Defendant"), allege as follows:

PARTIES

1. Plaintiff Mallinckrodt IP Unlimited Company ("Mallinckrodt IP Unlimited") is a company organized and existing under the laws of Ireland, having a registered address of College Business & Technology Park, Cruiserath, Blanchardstown, Dublin 15, Ireland. Mallinckrodt IP Unlimited is a wholly-owned subsidiary of Mallinckrodt plc. As set forth herein, Mallinckrodt IP Unlimited is the exclusive sub-licensee of U.S. Patent No. 6,992,218 ("the '218 patent), and the assignee of U.S. Patent Nos. 9,399,012 ("the '012 patent") and 9,610,265 ("the '265 patent") (collectively, the "patents-in-suit").

2. Plaintiff Mallinckrodt Hospital Products Inc. ("Mallinckrodt Hospital Products"), formerly Cadence Pharmaceuticals, Inc. ("Cadence"), is a corporation organized and existing

under the laws of Delaware, having a principal place of business at 675 McDonnell Blvd., Hazelwood, Missouri 63042. Mallinckrodt Hospital Products is a wholly-owned subsidiary of Mallinckrodt plc.

3. Plaintiff New Pharmatop L.P. ("New Pharmatop") is a business entity organized and existing under the laws of Delaware, having a principal place of business at 2711 Centerville Road, Suite #400, Wilmington, Delaware 19808. As set forth herein, New Pharmatop is the assignee of the '218 patent.

4. Upon information and belief, Defendant Aurobindo is a corporation organized and existing under the laws of Delaware, having a principal place of business at 279, Princeton-Highstown Rd., East Windsor, New Jersey 08520-1401 USA.

NATURE OF THE ACTION

5. This is a civil action for infringement of the patents-in-suit pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*; the Federal Food, Drug, and Cosmetic Act; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*.

JURISDICTION AND VENUE

6. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201(a).

7. This Court has personal jurisdiction over Aurobindo because, upon information and belief, Aurobindo is a corporation organized and existing under the laws of Delaware and maintains a registered agent for service of process in Delaware. This Court has personal jurisdiction over Aurobindo for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

8. Aurobindo has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware.

9. Upon information and belief, Aurobindo, directly or through its affiliates and agents, regularly and continuously transacts business within the State of Delaware, including by developing, formulating, manufacturing, marketing and selling pharmaceutical products, including generic drug products, throughout the United States and in Delaware. Upon information and belief, Aurobindo derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within the State of Delaware.

10. Upon information and belief, Aurobindo has registered with the Delaware Board of Pharmacy as a licensed "Pharmacy – Wholesale" under License No. A4-0001270. Upon information and belief, Aurobindo has also registered with the Delaware Board of Pharmacy as a licensed distributor/manufacturer under License No. DM0006550. Upon information and belief, Aurobindo has agreements with retailers, wholesalers, and/or distributors operating in the state of Delaware.

11. Upon information and belief, Aurobindo has previously consented to personal jurisdiction in this judicial district, including but not limited to *Sanofi et al. v. Aurobindo Pharma USA, Inc.*, No. 17-cv-1247-RGA (D. Del. 2017), and *Allergan, Inc. v. Aurobindo Pharma Ltd., et al.*, No. 17-cv-1290-GMS (D. Del. 2017).

12. Aurobindo has admitted that it "solicits business in Delaware." *See Sanofi, et al. v. Aurobindo Pharma USA, Inc.*, No. 17-cv-1247-RGA, D.I. 8 at ¶¶ 7, 9. Aurobindo also has admitted that "it has a Delaware controlled substance distributor/manufacturer license and a Delaware pharmacy wholesale license." *Id.* at ¶ 6.

13. This Court has personal jurisdiction over Aurobindo because, *inter alia*, upon information and belief, Aurobindo has submitted Abbreviated New Drug Application ("ANDA") No. 210969, claiming bioequivalence to Plaintiffs' OFIRMEV® injectable acetaminophen product and seeking nationwide approval of its proposed product. Aurobindo's submission of ANDA No. 210969 constitutes an act of infringement of the patents-in-suit pursuant to 35 U.S.C. § 271(e)(2). Aurobindo's tortious act of infringing the patents-in-suit causes concrete harm to Plaintiffs. By a letter received by Plaintiffs on or around November 21, 2017 (the "Aurobindo Letter"), Aurobindo stated that it had submitted ANDA No. 210969 seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of acetaminophen 1g/100 mL solution for IV infusion ("Aurobindo's ANDA Product") prior to the expiration of the patents-in-suit, and specifically intends to engage in the sale of Aurobindo's ANDA Product in the State of Delaware. Aurobindo's submission of ANDA No. 210969, claiming bioequivalence to Plaintiffs' OFIRMEV® injectable acetaminophen product and seeking nationwide approval of Aurobindo's ANDA Product, is an act of infringement of the patents-in-suit in Delaware pursuant to 35 U.S.C. § 271(e)(2) causing concrete harm to Plaintiffs

14. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) because Aurobindo is a Delaware corporation and therefore "resides" in this judicial district. *TC Heartland, LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017).

15. Venue is also proper in this judicial district for the additional reasons set forth below and for other reasons that will be presented to the Court if such venue is challenged. Under the Hatch-Waxman Act, the evaluation of infringement involves what the applicant will "likely market if its application is approved." *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248-49 (Fed. Cir. 2000) (citing *Glaxo, Inc. v. Novopharm, Ltd.*, 110 F.3d 1562,

1569 (Fed. Cir. 1997)). In addition, this Court has held that in the context of an action arising under the Hatch-Waxman Act, the filing of such an application is a formal act that reliably indicates plans to engage in marketing of its proposed generic drug in Delaware. Aurobindo's submission of ANDA No. 210969, claiming bioequivalence to Plaintiffs' OFIRMEV® injectable acetaminophen product and seeking nationwide approval of Aurobindo's ANDA Product, is an act of infringement of the patents-in-suit in Delaware pursuant to 35 U.S.C. § 271(e)(2) causing concrete harm to Plaintiffs.

16. Upon information and belief, Aurobindo has a regular and established place of business in Delaware because it "does business in that district through a permanent and continuous presence there." *See In re Cordis Corp.*, 769 F.2d 733, 737 (Fed. Cir. 1985). On information and belief, Aurobindo has a "physical place in the district," which is "a regular and established place of business," and is "the place of the defendant." *In re Cray*, 871 F.3d 1355, 1362 (Fed. Cir. 2017). Plaintiffs incorporate by reference and replead here preceding paragraphs 7-13 as showing Aurobindo's established place of business in Delaware.

17. Thus, upon information and belief, venue is proper in this judicial district under 28 U.S.C. § 1400(b).

18. This action involves patents that were at issue in other actions before this Court. The '218 patent was at issue in the actions captioned *Cadence Pharmaceuticals, Inc. v. Exela Pharma Sciences, LLC*, No. 11-733, *Cadence Pharmaceuticals, Inc. v. InnoPharma Licensing LLC*, No. 14-1225, and *Cadence Pharmaceuticals, Inc. v. Mylan Laboratories Ltd.*, No. 14-1499. The '012 patent was previously at issue before this Court in the actions captioned *Mallinckrodt IP v. InnoPharma Licensing LLC,* No. 16-1116, and *Mallinckrodt IP v. Mylan Laboratories Ltd.*, No. 16-1115. The '218 and '012 patents are currently at issue in the action captioned

Mallinckrodt IP Unlimited Company v. B. Braun Medical Inc., No. 17-365. The '012 and '265 patents are currently at issue in the action captioned *Mallinckrodt IP Unlimited Company v. B. Braun Medical Inc.*, No. 17-660.

THE PATENTS-IN-SUIT

19. The '218 patent, titled "Method for Obtaining Aqueous Formulations of Oxidation-Sensitive Active Principles," was duly and legally issued by the United States Patent and Trademark Office ("PTO") on January 31, 2006. The named inventors assigned the application which issued as the '218 patent to SCR Pharmatop.

20. SCR Pharmatop granted an exclusive license to the '218 patent to Bristol-Myers Squibb Company ("BMS") with a right to sublicense. BMS granted Cadence (now Mallinckrodt Hospital Products) a sublicense, which was exclusive even to BMS, to the '218 patent with regard to all rights pertinent hereto. As a result of the corporate restructuring following the purchase of Cadence by Mallinckrodt plc, Mallinckrodt IP Unlimited is the exclusive sub-licensee of the '218 patent.

21. SCR Pharmatop then assigned the '218 patent to New Pharmatop. A true and correct copy of the '218 patent is attached as Exhibit A.

22. Claim 1 of the '218 patent recites "[a] method for preparing an aqueous solution with an active [principle of phenolic] nature susceptible to oxidation, which is paracetamol, while preserving for a prolonged period, comprising deoxygenation of the solution by bubbling with at least one inert gas and/or placing under vacuum, until the oxygen content is below 2 ppm, and optionally the aforementioned aqueous solution with an active principle is topped with an inert gas atmosphere heavier than air and placed in a closed container in which the prevailing

pressure is 65,000 Pa maximum, and the oxygen content of the aqueous solution is below 2 ppm, and optionally the deoxygenation of the solution is completed by addition of an antioxidant.

23. Claim 19 of the ’218 Patent recites “[a]n aqueous solutions containing, as an active ingredient, a principle of phenolic nature susceptible to oxidation, preserved by the method of claim 1.”

24. The ’012 patent, titled “Reduced Dose Intravenous Acetaminophen,” was duly and legally issued by the PTO on July 26, 2016. The named inventors assigned the application that issued as the ’012 patent to Cadence, which subsequently assigned that application to Mallinckrodt IP (now Mallinckrodt IP Unlimited). Mallinckrodt IP Unlimited is now the sole assignee of the ’012 patent. A true and correct copy of the ’012 patent is attached as Exhibit B.

25. Claim 1 of the ’012 patent recites “[a] method for the treatment of pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, comprising administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen; and repeating said administration at least once at an interval of about 3 to about 5 hours.”

26. Claim 39 of the ’012 patent recites “[t]he method of claim 1, wherein the administered dose of acetaminophen is 650 mg, and further comprising repeating intravenous administration of 650 mg acetaminophen at least once at an interval of about 3 hours to about 5 hours.”

27. The ’265 patent, titled “Reduced Dose Intravenous Acetaminophen,” was duly and legally issued by the PTO on April 4, 2017. The named inventors assigned the application that issued as the ’265 patent to Cadence, which subsequently assigned that application to

Mallinckrodt IP (now Mallinckrodt IP Unlimited). Mallinckrodt IP Unlimited is now the sole assignee of the '265 patent. A true and correct copy of the '265 patent is attached as Exhibit C.

28. Claim 1 of the '265 patent recites "[a] method of treating pain in a human subject weighing at least 50 kg comprising: co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount a second pharmaceutical composition comprising an opioid analgesic; wherein the first pharmaceutical composition is administered to the subject intravenously."

29. Claim 7 of the '265 patent recites "[t]he method of claim 1, wherein the first pharmaceutical composition comprises about 650 mg of acetaminophen."

OFIRMEV®

30. Cadence obtained approval from the Food and Drug Administration (the "FDA") for NDA No. 022450 for OFIRMEV®, the first and only intravenous (IV) formulation of acetaminophen available in the United States. As part of the corporate restructuring resulting from the purchase of Cadence by Mallinckrodt plc, Mallinckrodt IP Unlimited is now the holder of NDA No. 022450. Mallinckrodt Hospital Products distributes OFIRMEV®.

31. OFIRMEV® was approved by the FDA on November 2, 2010. OFIRMEV® is indicated for the management of mild to moderate pain, management of moderate to severe pain with adjunctive opioid analgesics, and reduction of fever.

32. The publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book") identifies drug products approved on the basis of safety and effectiveness by the FDA under the Federal Food, Drug, and Cosmetic Act. Pursuant to

21 U.S.C. § 355(b)(1) and attendant FDA regulations, the patents-in-suit were timely listed in the Orange Book with respect to OFIRMEV®.

DEFENDANT'S INFRINGEMENT OF THE PATENTS-IN-SUIT

33. Upon information and belief, Aurobindo submitted ANDA No. 210969 to the FDA under the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of Aurobindo's ANDA Product prior to the expiration of the patents-in-suit, all of which are listed in the Orange Book with respect to OFIRMEV®.

34. The Aurobindo Letter states that Aurobindo has submitted ANDA No. 210969 seeking approval to engage in the commercial manufacture, use, sale or offer for sale, and/or importation of Aurobindo's ANDA Product prior to the expiration of the patents-in-suit.

35. The Aurobindo Letter also states that ANDA No. 210969 contains a certification under 21 U.S.C. § 355(j)(2)(A)(vii) (the "Paragraph IV certification") alleging that "each claim [of the patents-in-suit] is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described by Aurobindo's ANDA."

'218 Patent

36. Aurobindo's submission of ANDA No. 210969 to the FDA, including its Paragraph IV certification, constitutes an act of infringement of the '218 patent under 35 USC § 271(e)(2)(A). In the event that Aurobindo commercially manufactures, imports, uses, offers for sale, or sells Aurobindo's ANDA Product and/or induces or contributes to such conduct, said actions would constitute infringement of the '218 patent under 35 USC § 271(a), (b), and/or (c).

37. The Aurobindo Letter states that the "[i]n further respect of U.S. Patent No. 6,992,218, claims 1-19 of the patent are not infringed by Aurobindo's ANDA Product, as it does

not comprise a container which is stoppered under an inert gas atmosphere heavier than air, in such a way as to create within the container a maximum pressure of 65,000 Pa and the oxygen content of the aqueous solution is below 2 ppm, which is essential step of the process for making of paracetamol infusion product." Aurobindo Letter at 51 (emphasis in original).

38. The term "and optionally the aforementioned aqueous solution with an active principle is topped with an inert gas atmosphere heavier than air and placed in a closed container in which the prevailing pressure is 65,000 Pa maximum, and the oxygen content of the aqueous solution is below 2 ppm" in claim 1 of the '218 patent was previously construed to mean "may, but not necessarily, include the steps of putting the solution with an active principle in a container under an inert, heavier than air gas and pressure of less than 65,000 Pa and wherein the final dissolved oxygen content of the solution is below 2 ppm." *Cadence Pharm., Inc. v. Exela Pharma Sci., LLC*, No. 11-733-LPS, slip op. at 3 (D. Del. Aug. 22, 2012), *aff'd*, 780 F.3d 1364, 1372 (Fed. Cir. 2015).

39. Pursuant to statute, the Paragraph IV notice must "include a detailed statement of the factual and legal basis of the opinions that the patent is invalid or will not be infringed." *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II). The Aurobindo Letter provides no other purported basis for noninfringement of the claims of the '218 patent.

40. Further, upon information and belief, the only viable way of manufacturing an acetaminophen solution with prolonged stability is to deoxygenate the solution (or the equivalent thereof) to below 2 ppm oxygen. For instance, the proposed generic Exela Pharma Sciences product was found by this Court to have infringed claims of the '218 patent, and the Cadence product was deemed to be a commercial embodiment thereof. *See Cadence Pharm., Inc. v. Exela Pharma Scis., LLC*, No. 11-733, 2013 WL 11083853 (D. Del. Nov. 14, 2013), *aff'd*,

780 F.3d 1364 (Fed. Cir. 2015)). Wockhardt Bio AG ("Wockhardt") and Agila Specialties Inc. ("Agila") have stipulated to infringement of the '218 patent with regard to their proposed generic versions of OFIRMEV®. BMS; Cadence; Mallinckrodt; Wockhardt; Agila; Paddock Laboratories, Inc.; Fresenius Kabi USA, LLC; and Sandoz, Inc. have taken licenses to the '218 patent. And Perfalgan, the European counterpart of OFIRMEV®, is deoxygenated to below 2 ppm oxygen. *See Cadence*, 2013 WL 11083853, at *5, *33 n.34.

41. Upon information and belief, Aurobindo was aware of the '218 patent prior to filing ANDA No. 210969, and its actions render this an exceptional case under 35 U.S.C. § 285.

'012 Patent

42. Aurobindo's submission of ANDA No. 210969 to the FDA, including its Paragraph IV certification, constitutes an act of infringement of the '012 patent under 35 USC § 271(e)(2)(A). In the event that Aurobindo commercially manufactures, imports, uses, offers for sale, or sells Aurobindo's ANDA Product and/or induces such conduct, said actions would constitute infringement of the '012 patent under 35 USC § 271(a) and/or (b).

43. Pursuant to statute, the Paragraph IV notice must "include a detailed statement of the factual and legal basis of the opinions that the patent is invalid or will not be infringed." *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II). The Aurobindo Letter provides no purported basis for noninfringement of at least independent claims 1, 29, 48, and 79, and dependent claim 39, of the '012 patent.

44. Upon information and belief, the Aurobindo proposed labeling will contain recommendations and instructions as to dosing 650 mg of acetaminophen which will encourage, promote, and/or recommend the administration of, *inter alia*, said volume by medical personnel.

45. Upon further information and belief, Aurobindo will otherwise encourage, promote, and/or recommend the administration of Aurobindo's ANDA Product to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 550 mg to about 800 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours, which administration will constitute direct infringement of at least claim 1 of the '012 patent. Upon information and belief, this will occur at Aurobindo's active behest, and with Aurobindo's intent, knowledge, and encouragement. Upon information and belief, Aurobindo will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of Plaintiffs' rights under the '012 patent.

46. Upon further information and belief, Aurobindo will otherwise encourage, promote, and/or recommend the administration of Aurobindo's ANDA Product to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising 650 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours, which administration will constitute direct infringement of at least claim 39 of the '012 patent. Upon information and belief, this will occur at Aurobindo's active behest, and with Aurobindo's intent, knowledge, and encouragement. Upon information and belief, Aurobindo will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of Plaintiffs' rights under the '012 patent.

47. By filing ANDA No. 210969, Aurobindo has necessarily represented to the FDA that the components of Aurobindo's ANDA Product have the same active ingredient as that of the corresponding components of OFIRMEV®, have the same route of administration, dosage form, and strengths as the corresponding components of OFIRMEV®, and are bioequivalent to the corresponding components of OFIRMEV®.

48. The OFIRMEV® labeling includes instructions for administering OFIRMEV® to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising 650 mg of acetaminophen and repeating said administration at least once at an interval of 4 hours. A true and correct copy of the OFIRMEV® labeling is attached as Exhibit D.

49. For instance, Section 2.2 of the OFIRMEV® labeling recites that for adults and adolescents weighing 50 kg and over, "the recommended dosage of OFIRMEV is 1000 mg every 6 hours or 650 mg every 4 hours, with a maximum single dose of OFIRMEV of 1000 mg, a minimum dosing interval of 4 hours, and a maximum daily dose of acetaminophen of 4000 mg per day."

50. Table 1 of the OFIRMEV® labeling also contains recommended dosing information for adults and adolescents weighing 50 kg and over, reciting that the "[d]ose given every 4 hours" is "650 mg."

51. Section 2.5 of the OFIRMEV® labeling provides instructions and/or recommendations for dosing and recites, in pertinent part, that "[f]or doses less than 1000 mg, the appropriate dose must be withdrawn from the vial and placed into a separate container prior to administration. Using aseptic technique, withdraw the appropriate dose (650 mg or weight-

based) from an intact sealed OFIRMEV container and place the measured dose in a separate empty, sterile container (e.g., glass bottle, plastic intravenous container, or syringe) for intravenous infusion . . . ."

52. Section 6.1 of the OFIRMEV® labeling reports on clinical trials in which patients were administered 650 mg OFIRMEV® every 4 hours.

53. Section 14.1 of the OFIRMEV® labeling describes acute pain studies in adults in which patients were administered 650 mg OFIRMEV® every 4 hours. The OFIRMEV® labeling reports that patients receiving OFIRMEV® experienced a statistically significant greater reduction in pain intensity over 24 hours compared to placebo.

54. The OFIRMEV® labeling therefore instructs, recommends, promotes, and/or encourages medical care providers to practice the methods of at least claims 1 and 39 of the '012 patent.

55. The foregoing information in the OFIRMEV® labeling is essential for the safe and effective use of the drug, particularly given the warnings in the labeling concerning potential dosing errors. As the warning in the Highlights of Prescribing Information indicates, "[t]ake care when prescribing, preparing, and administering OFIRMEV Injection to avoid dosing errors which could result in accidental overdose and death." The Highlights continue: "Acetaminophen has been associated with cases of acute liver failure, at times resulting in liver transplant and death. Most of the cases of liver injury are associated with the use of acetaminophen at doses that exceed the recommended maximum daily limits . . . ."

56. Upon information and belief, Aurobindo was aware of the '012 patent prior to filing ANDA No. 210969, and its actions render this an exceptional case under 35 U.S.C. § 285.

’265 Patent

57. Aurobindo’s submission of ANDA No. 210969 to the FDA, including its Paragraph IV certification, constitutes an act of infringement of the ’265 patent under 35 USC § 271(e)(2)(A). In the event that Aurobindo commercially manufactures, imports, uses, offers for sale, or sells Aurobindo’s ANDA Product and/or induces such conduct, said actions would constitute infringement of the ’265 patent under 35 USC § 271(a) and/or (b).

58. Pursuant to statute, the Paragraph IV notice must “include a detailed statement of the factual and legal basis of the opinions that the patent is invalid or will not be infringed.” *See* 21 U.S.C. § 355(j)(2)(B)(iv)(II). The Aurobindo Letter provides no purported basis for noninfringement of at least independent claim 1 and dependent claim 7 of the ’265 patent.

59. Upon information and belief, Aurobindo’s proposed labeling will include recommendations regarding co-administration of, *inter alia*, 650 mg of acetaminophen with an opioid analgesic.

60. Upon further information and belief, Aurobindo will encourage, promote, and/or recommend the administration of Aurobindo’s ANDA Product to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 500 mg to about 750 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously, which co-administration will constitute direct infringement of at least claim 1 of the ’265 patent. Upon information and belief, this will occur at Defendant’s active behest, and with Defendant’s intent, knowledge, and encouragement. Upon information and belief,

Defendant will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of Plaintiffs' rights under the '265 patent.

61. Upon further information and belief, Aurobindo will encourage, promote, and/or recommend the administration of Aurobindo's ANDA Product to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 650 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously, which co-administration will constitute direct infringement of at least claim 7 of the '265 patent. Upon information and belief, this will occur at Defendant's active behest, and with Defendant's intent, knowledge, and encouragement. Upon information and belief, Defendant will actively induce, encourage, and abet this infringement with knowledge that it is in contravention of Plaintiffs' rights under the '265 patent.

62. Upon information and belief, Aurobindo will market Aurobindo's ANDA Product to hospitals, clinics, physicians, and other medical care providers and will promote, recommend, and/or encourage the practice of the steps of at least claims 1 and 7 of the '265 patent.

63. By filing ANDA No. 210969, Aurobindo has necessarily represented to the FDA that the components of Aurobindo's ANDA Product have the same active ingredient as that of the corresponding components of OFIRMEV®, have the same route of administration, dosage form, and strengths as the corresponding components of OFIRMEV®, and are bioequivalent to the corresponding components of OFIRMEV®.

64. The OFIRMEV® labeling includes instructions for administering OFIRMEV® to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in

need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising about 650 mg of acetaminophen and repeating said administration at least once at an interval of 4 hours. A true and correct copy of the OFIRMEV® labeling is attached as Exhibit D.

65. For example, Section 1 of the OFIRMEV® labeling provides that "OFIRMEV (acetaminophen) injection is indicated for the . . . Management of moderate to severe pain with adjunctive opioid analgesics."

66. Section 2.2 of the OFIRMEV® labeling recites that for adults and adolescents weighing 50 kg and over, "the recommended dosage of OFIRMEV is 1000 mg every 6 hours or 650 mg every 4 hours, with a maximum single dose of OFIRMEV of 1000 mg, a minimum dosing interval of 4 hours, and a maximum daily dose of acetaminophen of 4000 mg per day."

67. Table 1 of the OFIRMEV® labeling also contains recommended dosing information for adults and adolescents weighing 50 kg and over, reciting that the "[d]ose given every 4 hours" is "650 mg."

68. Section 2.5 of the OFIRMEV® labeling provides instructions and/or recommendations for dosing and recites, in pertinent part, that "[f]or doses less than 1000 mg, the appropriate dose must be withdrawn from the vial and placed into a separate container prior to administration. Using aseptic technique, withdraw the appropriate dose (650 mg or weight-based) from an intact sealed OFIRMEV container and place the measured dose in a separate empty, sterile container (e.g., glass bottle, plastic intravenous container, or syringe) for intravenous infusion . . . ."

69. Section 6.1 of the OFIRMEV® labeling reports on clinical trials in which patients were administered 650 mg OFIRMEV® every 4 hours.

70. Section 14.1 of the OFIRMEV® labeling describes acute pain studies in adults in which patients were administered 650 mg OFIRMEV® every 4 hours. The OFIRMEV® labeling reports that patients receiving OFIRMEV® experienced a statistically significant greater reduction in pain intensity over 24 hours compared to placebo.

71. The OFIRMEV® labeling therefore instructs, recommends, promotes, and/or encourages medical care providers to practice the methods of at least claims 1 and 7 of the '265 patent.

72. The foregoing information in the OFIRMEV® labeling is essential for the safe and effective use of the drug, particularly given the warnings in the labeling concerning potential dosing errors.

73. Upon information and belief, Aurobindo was aware of the '265 patent prior to filing ANDA No. 210969, and its actions render this an exceptional case under 35 U.S.C. § 285.

COUNT I
(INFRINGEMENT OF THE '218 PATENT)

74. Plaintiffs incorporate each of the preceding paragraphs 1 to 73 as if fully set forth herein.

75. Aurobindo's submission of ANDA No. 210969, including its Paragraph IV certification, constitutes infringement of the '218 patent pursuant to 35 U.S.C. § 271(e)(2).

76. Upon information and belief, upon FDA approval of ANDA No. 210969, Aurobindo will infringe at least claims 1 and 19 of the '218 patent by making, using, offering to sell, or selling Aurobindo's ANDA Product in the United States, and/or importing Aurobindo's ANDA Product into the United States, and by actively inducing and/or contributing to infringement by others, in violation of 35 U.S.C. § 271.

77. Upon information and belief, Aurobindo had actual and constructive knowledge of the '218 patent prior to filing of ANDA No. 210969 and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '218 patent.

COUNT II
(DECLARATORY JUDGEMENT OF INFRINGEMENT OF THE '218 PATENT)

78. Plaintiffs incorporate each of the preceding paragraphs 1 to 77 as if fully set forth herein.

79. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

80. Plaintiffs are further entitled to a declaration that, if Aurobindo, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells Aurobindo's ANDA Product within the United States, imports Aurobindo's ANDA Product into the United States, or induces or contributes to such conduct, Aurobindo would infringe the '218 patent under 35 U.S.C. § 271(a), (b), and/or (c).

81. An actual controversy has arisen and now exists between the parties concerning whether Aurobindo will directly or indirectly infringe the '218 patent.

82. Plaintiffs are entitled to an injunction restraining and enjoining Aurobindo and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of Aurobindo's ANDA Product until the expiration of the '218 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

83. Plaintiffs will be irreparably harmed by Aurobindo's infringing activities unless those activities are enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

COUNT III
(INFRINGEMENT OF THE '012 PATENT)

84. The Mallinckrodt Plaintiffs incorporate each of the preceding paragraphs 1 to 83 as if fully set forth herein.

85. Aurobindo's submission of ANDA No. 210969, including its Paragraph IV certification, constitutes infringement of the '012 patent pursuant to 35 U.S.C. § 271(e)(2).

86. Upon information and belief, upon FDA approval of ANDA No. 210969, Aurobindo will induce infringement of at least claims 1 and 39 of the '012 patent by making, using, offering to sell, or selling Aurobindo's ANDA Product in the United States, and/or importing Aurobindo's ANDA Product into the United States, and by actively inducing infringement by others, in violation of 35 U.S.C. § 271.

87. Upon information and belief, upon FDA approval of ANDA No. 210969, doctors, nurses, and other medical professionals will directly infringe at least claims 1 and 39 of the '012 patent by using Aurobindo's ANDA Product, in violation of 35 U.S.C. § 271(a). Aurobindo's ANDA Product will be administered to treat pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising 650 mg of acetaminophen and repeating said administration at least once at an interval of 4 hours, which administration will constitute direct infringement of at least claims 1 and 39 of the '012 patent. Additionally, Aurobindo will otherwise promote, encourage, and/or instruct use of Aurobindo's ANDA Product for treating pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a

pharmaceutical composition comprising 650 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours.

88. Upon information and belief, this direct infringement will occur at Aurobindo's active behest, and with Aurobindo's intent, knowledge, and encouragement. Aurobindo will intentionally encourage infringement of at least claims 1 and 39 of the '012 patent by at least making, using, offering to sell, or selling Aurobindo's ANDA Product and by recommending and/or instructing use of Aurobindo's ANDA Product. Furthermore, Aurobindo will intentionally encourage infringement of at least claims 1 and 39 of the '012 patent at least by way of the labeling for Aurobindo's ANDA Product which will contain recommendations and/or instructions for treating pain or fever in an adult human or an adolescent human subject weighing at least 50 kg, in need thereof, by administering to the subject, by an intravenous route of administration, a therapeutically effective amount of a pharmaceutical composition comprising 650 mg of acetaminophen and repeating said administration at least once at an interval of about 3 to about 5 hours.

89. Upon information and belief, Aurobindo is aware of the '012 patent, which is listed in the Orange Book with respect to OFIRMEV®, and Aurobindo will actively induce, encourage, and abet this infringement with knowledge that such conduct is in contravention of the Mallinckrodt Plaintiffs' rights under the '012 patent, in violation of 35 U.S.C. § 271(b).

90. Upon information and belief, Aurobindo had actual and constructive knowledge of the '012 patent prior to filing ANDA No. 210969 and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '012 patent.

COUNT IV
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '012 PATENT)

91. The Mallinckrodt Plaintiffs incorporate each of the preceding paragraphs 1 to 90 as if fully set forth herein.

92. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

93. The Mallinckrodt Plaintiffs are entitled to a declaration that, if Aurobindo, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells Aurobindo's ANDA Product within the United States, imports Aurobindo's ANDA Product into the United States, or induces such conduct, Aurobindo would infringe the '012 patent under 35 U.S.C. § 271(a) and/or (b).

94. An actual controversy has arisen and now exists between the parties concerning whether Aurobindo will directly or indirectly infringe the '012 patent.

95. The Mallinckrodt Plaintiffs are entitled to an injunction restraining and enjoining Aurobindo and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of Aurobindo's ANDA Product until the expiration of the '012 patent, including any extensions and/or additional periods of exclusivity to which the Mallinckrodt Plaintiffs are or become entitled.

96. The Mallinckrodt Plaintiffs will be irreparably harmed by Aurobindo's infringing activities unless those activities are enjoined by this Court. The Mallinckrodt Plaintiffs do not have an adequate remedy at law.

COUNT V
(INFRINGEMENT OF THE '265 PATENT)

97. The Mallinckrodt Plaintiffs incorporate each of the preceding paragraphs 1 to 96 as if fully set forth herein.

98. Aurobindo's submission of ANDA No. 210969, including its Paragraph IV certification, constitutes infringement of the '265 patent pursuant to 35 U.S.C. § 271(e)(2).

99. Upon information and belief, upon FDA approval of ANDA No. 210969, Aurobindo will induce infringement of at least claims 1 and 7 of the '265 patent by making, using, offering to sell, or selling Aurobindo's ANDA Product in the United States, and/or importing Aurobindo's ANDA Product into the United States, and by actively inducing infringement by others, in violation of 35 U.S.C. § 271(b).

100. Upon information and belief, upon FDA approval of ANDA No. 210969, doctors, nurses, and other medical professionals will directly infringe at least claims 1 and 7 of the '265 patent by using Aurobindo's ANDA Product, in violation of 35 U.S.C. § 271(a). Aurobindo's ANDA Product will be administered to treat pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 650 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously, which co-administration will constitute direct infringement of at least claims 1 and 7 of the '265 patent. Additionally, Aurobindo will otherwise promote, encourage, and/or instruct use of Aurobindo's ANDA Product for treating pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 650 mg of acetaminophen and a therapeutically effective amount of a second

pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously.

101. Upon information and belief, this direct infringement will occur at Aurobindo's active behest, and with Aurobindo's intent, knowledge, and encouragement. Aurobindo will intentionally encourage infringement of at least claims 1 and 7 of the '265 patent by at least making, using, offering to sell, or selling Aurobindo's ANDA Product and by recommending and/or instructing use of Aurobindo's ANDA Product. Furthermore, Aurobindo will intentionally encourage infringement of at least claims 1 and 7 of the '265 patent at least by way of the labeling for Aurobindo's ANDA Product which will contain recommendations and/or instructions for treating pain in a human subject weighing at least 50 kg by co-administering to the subject a therapeutically effective amount of a first pharmaceutical composition comprising about 650 mg of acetaminophen and a therapeutically effective amount of a second pharmaceutical composition comprising an opioid analgesic, wherein the first pharmaceutical composition is administered to the subject intravenously.

102. Upon information and belief, Aurobindo is aware of the '265 patent, which is listed in the Orange Book with respect to OFIRMEV®, and Aurobindo will actively induce, encourage, and abet this infringement with knowledge that such conduct is in contravention of the Mallinckrodt Plaintiffs' rights under the '265 patent, in violation of 35 U.S.C. § 271(b).

103. Upon information and belief, Aurobindo had actual and constructive knowledge of the '265 patent prior to filing ANDA No. 210969 and acted without a reasonable basis for a good faith belief that it would not be liable for infringing the '265 patent.

COUNT VI
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '265 PATENT)

104. The Mallinckrodt Plaintiffs incorporate each of the preceding paragraphs 1 to 103 as if fully set forth herein.

105. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

106. The Mallinckrodt Plaintiffs are entitled to a declaration that, if Aurobindo, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells Aurobindo's ANDA Product within the United States, imports Aurobindo's ANDA Product into the United States, or induces such conduct, Aurobindo would infringe the '265 patent under 35 U.S.C. § 271(a) and/or (b).

107. An actual controversy has arisen and now exists between the parties concerning whether Aurobindo will directly or indirectly infringe the '265 patent.

108. The Mallinckrodt Plaintiffs are entitled to an injunction restraining and enjoining Aurobindo and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of Aurobindo's ANDA Product until the expiration of the '265 patent, including any extensions and/or additional periods of exclusivity to which the Mallinckrodt Plaintiffs are or become entitled.

109. The Mallinckrodt Plaintiffs will be irreparably harmed by Aurobindo's infringing activities unless those activities are enjoined by this Court. The Mallinckrodt Plaintiffs do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that Aurobindo infringed and is infringing each of the patents-in-suit;

B. An order issued pursuant to 35 U.S.C. § 271(e)(4) that the effective date of any approval of Aurobindo's ANDA No. 210969 shall not be earlier than the expiration date of the patents-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled; a declaration that if Aurobindo, prior to patent expiry, commercially manufactures, uses, offers for sale, or sells Aurobindo's ANDA Product within the United States, imports Aurobindo's ANDA Product into the United States, or induces such conduct, Aurobindo would infringe the patents-in-suit;

C. A preliminary and permanent injunction restraining and enjoining Aurobindo and its officers, agents, attorneys and employees, and those acting in privity or concert with it, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States of any of Aurobindo's ANDA Product until the expiration of the patents-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

D. That Plaintiffs be awarded monetary relief of not less than a reasonable royalty if Aurobindo commercially manufactures, uses, offers for sale, or sells its generic version of Plaintiffs' OFIRMEV® brand product, or any other product that infringes or induces the infringement of the patents-in-suit, within the United States before the latest expiration date of the patents-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or becomes entitled;

E. A declaration that this is an exceptional case and an award of expenses including attorneys' fees pursuant to 35 U.S.C. § 285;

F. An award of costs in this action; and

G. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Thomas C. Grimm

Thomas C. Grimm (#1098)
Jeremy A. Tigan (#5239)
Stephen J. Kraftschik (#5623)
1201 N. Market Street
P.O. Box 1347
Wilmington, DE 19899-1347
(302) 658-9200
tgrimm@mnat.com
jtigan@mnat.com
skraftschik@mnat.com
Attorneys for Mallinckrodt IP Unlimited Company, Mallinckrodt Hospital Products Inc., and New Pharmatop L.P.

OF COUNSEL:

Kenneth G. Schuler
Marc N. Zubick
Sarah W. Wang
LATHAM & WATKINS LLP
330 North Wabash Avenue, Suite 2800
Chicago, IL 60611
(312) 876-7700

Daniel G. Brown
Michelle Ernst
LATHAM & WATKINS LLP
885 Third Avenue
New York, NY 10022
(212) 906-1200

Gregory K. Sobolski
LATHAM & WATKINS LLP
505 Montgomery Street, Suite 2000
San Francisco, CA 94111
(415) 391-0600

Attorneys for Mallinckrodt IP Unlimited Company and Mallinckrodt Hospital Products Inc.

Brian T. Moriarty
Lawrence P. Cogswell, III, Ph.D.
HAMILTON, BROOK, SMITH
& REYNOLDS, P.C.
Seaport West
155 Seaport Boulevard
Boston, MA 02210
(617) 607-5900

Attorneys for New Pharmatop L.P.

December 29, 2017
11555813